



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

Tuesday, September 25, 2007

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No.: 777-66  
DP Barcode: D341450

To: Velma Noble, PM 31/ Demetrius Armstead  
Regulatory Management Branch  
Antimicrobials Division (7510P)

From: Ian Blackwell, Biologist  
Chemistry and Toxicology Team  
Product Science Branch  
Antimicrobials Division (7510P)

Through: Karen Hicks, Team Leader  
Chemistry and Toxicology Team  
Product Science Branch  
Antimicrobials Division (7510P)

Michele E. Wingfield, Chief  
Product Science Branch  
Antimicrobials Division (7510P)

Applicant: Reckitt Benckiser, Inc.

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Alkyl (67% C12, 25% C14, 7% C16, 1% C8-C10-C18) dimethyl benzyl ammonium chlorides	0.0860
Alkyl (50% C14, 40% C12, 10% C16) dimethyl benzyl ammonium chlorides	0.0216
<u>Other Ingredient(s):</u>	<u>99.8924</u>
Total:	100.0000

"Causes substantial, but temporary, eye injury. Do not get in eyes or on clothing. Wear goggles, face shield or safety glasses. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using restroom. Remove and wash contaminated clothing before reuse. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals."

c) The First Aid statements must state:

**If in Eyes:**

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
- Call a Poison Control Center or doctor for treatment advice.

d) The submitted label contains First Aid statements for dermal exposure (acute dermal toxicity and/or primary skin irritation) and acute oral toxicity. Based upon the results of the submitted studies, these statements are not required. However, the registrant may retain these statements if they feel the need to do so.

## DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (OPPTS 870.1100)

**Product Manager:** 31  
**MRID No.:** 471560-05

**Reviewer:** CSC and Ian Blackwell  
**Completion Date:** January 5, 2006  
**Report No.:** 9546-05

**Testing Laboratory:** STILLMEADOW, Inc., Sugar Land, TX  
**Author:** Janice O. Kuhn, Ph.D., D.A.B.T.

**Quality Assurance (40 CFR §160.12):** A Quality Assurance statement was included. A statement of Good Laboratory Practice (GLP) compliance was included stating that the study was designed and performed in STILLMEADOW, Inc.'s laboratory and was conducted in compliance with U.S. EPA FIFRA 40 CFR 160, with the following exception: "Sec. 160.31(d) and 160.105(a)(b)(e) characterization and stability information was not provided in a Certificate of Analysis."

**Test Material:** Lysol All Purpose Cleaner Trigger Lemon, EPA Reg. No. 777-66  
Batch #: 1102-149 / Yellow liquid

**Dosage:** 5,000 mg/kg (administered as received and was not diluted)

**Species:** 3 Rats; Sprague-Dawley, albino  
**Sex:** Female. Females were nulliparous and non-pregnant.  
**Age:** Approximately 7-9 weeks old  
**Weight:** 159-169 grams; fasted weight on dosing day  
**Source:** Texas Animal Specialties, Humble, TX  
**Housing:** Temperature Range: 22±3°C  
Humidity Range: 30-70%  
Photoperiod: 12-hour light/dark cycle

**Acclimation:** 5 days

### Conclusion:

1. **LD<sub>50</sub> (mg/kg):** Female Rats: >5,000 mg/kg
2. **Toxicity Category:** IV **Classification:** Acceptable

### Procedure (Deviations from 870.1100):

- The laboratory reported that "there were no deviations from the protocol that affected the quality or outcome of the study."
- The guidelines state that, at the commencement of dosing, each animal should be between 8 weeks and 12 weeks old. The animals were between 7 and 9 weeks old.
- The guidelines state that animals should be observed individually at least once during the first 30 minutes after dosing. The animals were observed at least three times on Day 0; however, the laboratory did not indicate that one of these three times was "during the first 30 minutes after dosing."
- Individual body weights of test animals were recorded; however, changes in body weights were not reported.

**Results:****Reported Mortality**

<b>Dosage (mg/kg)</b>	<b>Number Deaths / Number Tested</b>
5,000	0 / 3

**Observations:**

No mortality occurred during the study. Body weight gain was unaffected by the administration of the test substance. All animals appeared normal for the duration of the study.

**Gross Necropsy Findings:**

The gross necropsy conducted at termination of the study revealed no observable abnormalities.

## DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (OPPTS 870.1200)

**Product Manager:** 31  
**MRID No.:** 471560-06

**Reviewer:** CSC and Ian Blackwell  
**Completion Date:** January 6, 2006  
**Report No.:** 9547-05

**Testing Laboratory:** STILLMEADOW, Inc., Sugar Land, TX  
**Author:** Janice O. Kuhn, Ph.D., D.A.B.T.

**Quality Assurance (40 CFR §160.12):** A Quality Assurance (QA) statement was included. A statement of Good Laboratory Practice (GLP) compliance was included stating that this study was designed and performed in STILLMEADOW, Inc.'s laboratory and was conducted in compliance with U.S. EPA FIFRA 40 CFR 160 with the following exception: "Sec. 160.31(d) and 160.105(a)(b)(e) characterization and stability information was not provided in a Certificate of Analysis."

**Test Material:** Lysol All Purpose Cleaner Trigger Lemon, EPA Reg. No. 777-66  
Batch #: 1102-149 / Yellow liquid

**Dosage:** 5,050 mg/kg (undiluted)

**Species:** 10 Rabbits; New Zealand White, albino  
**Sex:** 5 Males and 5 Females. Females were nulliparous and non-pregnant.  
**Age:** Approximately 21 weeks old  
**Weight:** Males: 2.050-2.400 kilograms; Females: 2.125-2.400 kilograms; on dosing day  
**Source:** Nichols Rabbitry, Inc., Lumberton, TX  
**Housing:** Temperature: 20±3°C  
Humidity: 30-70%  
Photoperiod: 12-hour light/dark cycle  
**Acclimation:** 5 days

### Summary:

- 1. Acute Dermal LD<sub>50</sub> (mg/kg):** Male and Female Rabbits: >5,050 mg/kg
- 2. The estimated acute dermal LD<sub>50</sub> is greater than 5,050 mg/kg in male and female rabbits.**
- 3. Toxicity Category:** IV **Classification:** Acceptable

### Procedure (Deviations from 870.1200):

- The laboratory reported that "there were no deviations from the protocol that affected the quality or outcome of the study."
- The guidelines state that after completion of the study in one sex, at least one group of five animals of the other sex is dosed to establish that animals of this sex are not markedly more sensitive to the test substance. The laboratory treated both the male and female groups within 10 minutes of each other.
- Individual body weights of test animals were recorded; however, changes in body weights were not reported.

**Results:****Reported Mortality**

Dose Level (mg/kg)	Number Dead / Number Tested		
	Males	Females	Total
5,050	0 / 5	0 / 5	0 / 10

**Observations:**

No mortality occurred during the study. Body weight gain was unaffected by the administration of the test substance, with the exception of one male and one female that lost weight between Days 7 and 14. All animals appeared normal for the duration of the study. Irritation included very slight erythema on Days 1 and 4 and desquamation on Days 7-14.

**Gross Necropsy Findings:**

The gross necropsy conducted at termination of the study revealed no observable abnormalities.

**DATA REVIEW FOR ACUTE INHALATION TOXICITY TESTING (OPPTS  
870.1300)  
(NOSE-ONLY EXPOSURE)**

**Product Manager:** 31  
**MRID No.:** 471560-07

**Reviewer:** CSC and Ian Blackwell  
**Completion Date:** January 23, 2006  
**Report No.:** 9548-05

**Testing Laboratory:** STILLMEADOW, Inc., Sugar Land, TX  
**Author:** Lori Carter, B.A.

**Quality Assurance (40 CFR §160.12):** A Quality Assurance (QA) statement was included. A statement of Good Laboratory Practice (GLP) compliance was included stating that this study was designed and performed in STILLMEADOW, Inc.'s laboratory and was conducted in compliance with U.S. EPA FIFRA 40 CFR 160 with the following exception: "Sec. 160.31(d) and 160.105(a)(b)(e) characterization and stability information was not provided in a Certificate of Analysis."

**Test Material:** Lysol All Purpose Cleaner Trigger Lemon, EPA Reg. No. 777-66  
Batch #: 1102-149 / Yellow liquid

**Species:** 10 Rats; Sprague-Dawley, albino  
**Sex:** 5 Males and 5 Females. Females were nulliparous and non-pregnant.  
**Age:** Young adult (9-10 weeks old)  
**Source:** Texas Animal Specialties, Humble, TX  
**Weight:** Males: 328-377 grams; Females: 196-223 grams; when tested  
**Housing:** Temperature: 22±2°C  
Humidity: 30-70%  
Photoperiod: 12-hour light/dark cycle

**Acclimation:** 5 days

**Concentration:**

Group	Analytical Exposure Concentration (mg/L)	Nominal Concentration (mg/L)
I	2.27	4.75

**Summary:**

- 1. LC<sub>50</sub> (mg/L) 4-hr exposure:** >2.27 mg/L in male and female rats.
- 2. The estimated 4-hr acute Inhalation LC<sub>50</sub> of Lysol All Purpose Cleaner Trigger Lemon, EPA Reg. No. 777-66 is greater than 2.27 mg/L in male and female rats.**
- 3. Average MMAD:** 1.9 µm
- 4. Toxicity Category:** IV      **Classification:** Acceptable

**Procedure (Deviations from 870.1300):**

- The laboratory reported that "there were no deviations from the protocol that affected the quality or outcome of the study."
- The guidelines state that after completion of the study in one sex, at least one group of five animals of the other sex should be exposed to establish that

animals of this sex are not markedly more sensitive to the test substance. The laboratory treated both the male and female groups simultaneously.

- The laboratory did not indicate whether animals were acclimated to exposure conditions and heat stress minimized.
- The guidelines state that three to four measurements should be taken during exposure if chamber concentration values and MMAD values taken during the trial run measurements are not within 10 percent of each other. The laboratory reported three trial run chamber concentration values which were not within the range sufficient to warrant just two measurements during exposure. In addition, only one MMAD value was reported during the trial run. The laboratory conducted only two sample measurements during the test, instead of the three to four measurements recommended in the guidelines.
- Individual body weights of test animals were recorded; however, changes in body weights were not calculated.

#### Results:

##### Reported Mortality

Exposure Concentration (mg/L)	Number Dead / Number Tested		
	Males	Females	Total
2.27	0 / 5	0 / 5	0 / 10

##### Chamber Atmosphere

Exp. Conc.	Sample	MMAD (µm)	GSD (µ)	Cumulative % of Particles < Size Range (µm)								
				0.0	0.3	0.5	0.9	1.6	2.5	4.2	10.	17.
2.27	1	1.6	4.5	0.00	0.00	0.00	43.7	62.5	75.0	75.0	100.	100.
	2	2.2	7.8	0.00	14.2	14.2	28.5	50.0	50.0	71.4	78.5	85.7

##### Chamber Environment During Exposure

Exposure Level (mg/L)	2.27
Chamber Volume (L)	500
Average Total Airflow (Lpm)	184
Number of Air Changes Per Hour	22.1
Oxygen Content (%)	≤19% of the exposure atmosphere
Mean Temperature (°C)	20
Mean Relative Humidity (%)	31

#### Clinical Observations:

There was no mortality during the study. Body weight gain in animals was unaffected by the administration of the test substance. Prominent in-life



observations included activity decrease and piloerection in both sexes on the day of dosing only.

**Gross Necropsy Findings:**

The gross necropsy conducted on each animal at termination of the study revealed no observable abnormalities except discolored lungs in four males and all females.

**Statistical Analysis:**

In order to calculate a mean exposure, the Mean Value Theorem of Calculus was used to properly weight the concentration since the concentrations could not be measured continuously. This method weights concentrations based on the time span of each concentration. A concentration can be calculated for each minute, which better represents the exposure concentration received by each animal.

## DATA REVIEW FOR ACUTE EYE IRRITATION TESTING (OPPTS 870.2400)

**Product Manager:** 31  
**MRID No.:** 471560-08

**Reviewer:** CSC and Ian Blackwell  
**Completion Date:** January 5, 2006  
**Report No.:** 9549-05

**Testing Laboratory:** STILLMEADOW, Inc., Sugar Land, TX  
**Author:** Janice O. Kuhn, Ph.D., D.A.B.T.

**Quality Assurance (40 CFR §160.12):** A Quality Assurance (QA) statement was included. A statement of Good Laboratory Practice (GLP) compliance was included stating that this study was designed and performed in STILLMEADOW, Inc.'s laboratory and was conducted in compliance with U.S. EPA FIFRA 40 CFR 160 with the following exception: "Sec. 160.31(d) and 160.105(a)(b)(e) characterization and stability information was not provided in a Certificate of Analysis."

**Test Material:** Lysol All Purpose Cleaner Trigger Lemon, EPA Reg. No. 777-66  
Batch #: 1102-149 / Yellow liquid

**Dosage:** 0.1 mL (undiluted)

**Species:** 3 Rabbits; New Zealand White, albino  
**Sex:** 1 Male and 2 Females  
**Age:** Approximately 17 weeks old  
**Weight:** Male: 2.250 kilograms; Females: 2.125-2.500 kilograms  
**Source:** Nichols Rabbitry, Inc., Lumberton, TX  
**Housing:** Temperature: 20±3°C  
Humidity: 30-70%  
Photoperiod: 12-hour light/dark cycle

**Acclimation:** 5 days

### Summary:

1. **Toxicity Category:** II
2. **Classification:** Acceptable

### Procedure (Deviations from 870.2400):

- The laboratory reported that "there were no deviations from the protocol that affected the quality or outcome of the study."
- The laboratory stated that "the treated eyes were anesthetized prior to dosing"; however the laboratory did not indicate whether the untreated left eyes that served as comparative controls were similarly anesthetized.

### Results:

The maximum average irritation score of 57.0, obtained at 24 hours after treatment, was used to rate the test substance severely irritating. Fluorescein staining was observed in all three eyes at 24 hours after treatment and was not observed in any eyes on Day 7 after treatment. Because all "positive" effects had cleared on Day 10 after dosing, the test substance is assigned to Toxicity Category II. No irritation was observed in any eyes on Day 14.

### Incidence of Irritation

Time Post Instillation	No. of Animals Testing "Positive" / No. of Animals Tested			
	Corneal Opacity	Iritis	Conjunctivae	
			Redness	Chemosis
1 hour	3 / 3	3 / 3	3 / 3	3 / 3
24 hours	3 / 3	3 / 3	3 / 3	3 / 3
48 hours	3 / 3	2 / 3	2 / 3	1 / 3
72 hours	1 / 3	1 / 3	1 / 3	1 / 3
Day 4	1 / 3	1 / 3	0 / 3	1 / 3
Day 7	0 / 3	1 / 3	0 / 3	1 / 3
Day 10	0 / 3	0 / 3	0 / 3	0 / 3
Day 14	0 / 3	0 / 3	0 / 3	0 / 3

### Individual Scores for Ocular Irritation

Observations	Rabbit No.: 9458 (Male)							
	Hours After Treatment				Days After Treatment			
	1	24	48	72	4	7	10	14
I. Corneal Opacity	1	2	2	1	3	0	0	0
II. Iris	1	1	1	1	1	1	0	0
III. Conjunctivae								
A. Redness	2	2	2	2	1	1	1	0
B. Chemosis	2	2	2	2	2	2	1	0
C. Discharge	2	2	2	1	2	1	0	0
Observations	Rabbit No.: 9349 (Female)							
	Hours After Treatment				Days After Treatment			
	1	24	48	72	4	7	10	14
I. Corneal Opacity	1	2	2	*	0	0	0	0
II. Iris	1	1	0	0	0	0	0	0
III. Conjunctivae								
A. Redness	2	2	1	1	0	0	0	0
B. Chemosis	2	2	1	1	0	0	0	0
C. Discharge	2	2	0	0	0	0	0	0
Observations	Rabbit No.: 9457 (Female)							
	Hours After Treatment				Days After Treatment			
	1	24	48	72	4	7	10	14
I. Corneal Opacity	1	2	2	0	0	0	0	0
II. Iris	1	1	1	0	0	0	0	0
III. Conjunctivae								
A. Redness	2	2	2	1	0	0	0	0
B. Chemosis	2	2	1	0	0	0	0	0
C. Discharge	2	2	0	0	0	0	0	0

\* - Slight dulling of normal luster

## **DATA REVIEW FOR ACUTE DERMAL IRRITATION TESTING (OPPTS 870.2500)**

**Product Manager:** 31  
**MRID No.:** 471560-09

**Reviewer:** CSC and Ian Blackwell  
**Completion Date:** January 5, 2006  
**Report No.:** 9550-05

**Testing Laboratory:** STILLMEADOW, Inc., Sugar Land, TX  
**Author:** Janice O. Kuhn, Ph.D., D.A.B.T.

**Quality Assurance (40 CFR §160.12):** A Quality Assurance statement was included. A statement of Good Laboratory Practice (GLP) compliance was included stating that the study was designed and performed in STILLMEADOW, Inc.'s laboratory and was conducted in compliance with U.S. EPA FIFRA 40 CFR 160, with the following exception: "Sec. 160.31(d) and 160.105(a)(b)(e) characterization and stability information was not provided in a Certificate of Analysis."

**Test Material:** Lysol All Purpose Cleaner Trigger Lemon, EPA Reg. No. 777-66  
Batch #: 1102-149 / Yellow liquid

**Dosage:** 0.5 mL (undiluted)

**Species:** 3 Rabbits; New Zealand White, albino  
**Sex:** 2 Males and 1 Female  
**Age:** Approximately 22 weeks old  
**Weight:** Males: 2.050-2.300 kilograms; Female: 2.250 kilograms  
**Source:** Nichols Rabbitry, Inc., Lumberton, TX  
**Housing:** Temperature: 20±3°C  
Humidity: 30-70%  
Photoperiod: 12-hour light/dark cycle

**Acclimation:** 5 days

### **Summary:**

1. **Toxicity Category:** IV
2. **Classification:** Acceptable

### **Procedure (Deviations from 870.2500):**

- The laboratory reported that "there were no deviations from the protocol that affected the quality or outcome of the study."

### **Results:**

Erythema and edema were not observed at any time throughout the study. No other signs of irritation were observed during the study.

The primary irritation index of 0.0 out of a possible 8.0 was obtained from the 1, 24, 48 and 72- hour observations and was used to give the test substance a descriptive rating of non-irritating. Based on the 72-hour observations only, the test substance is assigned to Toxicity Category IV.

### Incidence of Irritation

	No. of Animals Testing "Positive" / No. of Animals Tested	
Time after Patch Removal	Erythema	Edema
1 hour	0 / 3	0 / 3
24 hours	0 / 3	0 / 3
48 hours	0 / 3	0 / 3
72 hours	0 / 3	0 / 3

### Individual Skin Irritation Scores

Animal No.	Erythema				Edema				Primary Irritation Scores
	Time After Patch Removal								
	Hours				Hours				
	1	24	48	72	1	24	48	72	
9460-M	0	0	0	0	0	0	0	0	0.00
9462-M	0	0	0	0	0	0	0	0	0.00
9461-F	0	0	0	0	0	0	0	0	0.00
Primary Irritation Index* = 0.00 / 3									0.0

**DATA REVIEW FOR SKIN SENSITIZATION TESTING (OPPTS 870.2600)**  
(LOCAL LYMPH NODE ASSAY)

**Product Manager:** 31  
**MRID No.:** 471688-01

**Reviewer:** CSC and Ian Blackwell  
**Completion Date:** January 13, 2006  
**Report No.:** 9551-05

**Testing Laboratory:** STILLMEADOW, Inc., Sugar Land, TX  
**Author:** Janice O. Kuhn, Ph.D., D.A.B.T.

**Quality Assurance (40 CFR §160.12):** A Quality Assurance statement was included. A statement of Good Laboratory Practice (GLP) compliance was included stating that the study was designed and performed in STILLMEADOW, Inc.'s laboratory and was conducted in compliance with U.S. EPA FIFRA 40 CFR 160, with the following exceptions: "Sec. 160.113(a) mixture analysis was not performed and Sec. 160.31(d) and 160.105(a)(b)(e) characterization and stability information was not provided in a Certificate of Analysis."

**Test Material:** Lysol All Purpose Cleaner Trigger Lemon, EPA Reg. No. 777-66  
Batch #: 1102-149 / Yellow liquid

**Positive Control Material:** 80% (v/v) Alpha-Hexylcinnamaldehyde, tech. in 80%  
acetone: 20% olive oil

**Vehicle:** 80% acetone: 20% olive oil

**Species:** 25 Mice; CBA/J  
**Sex:** Vehicle Control Group: 5 Females  
Test Group I (25% concentration of test substance): 5 Females  
Test Group II (50% concentration of test substance): 5 Females  
Test Group III (100% concentration of test substance): 5 Females  
Positive Control Group: 5 Females  
**Age:** Approximately 8-9 weeks old  
**Weight:** 20.0-24.5 grams on initial dose day  
**Source:** Harlan Sprague-Dawley, Indianapolis, IN  
**Housing:** Temperature: 21±3°C  
Humidity: 30-70%  
Photoperiod: 12-hour light/dark cycle  
**Acclimation:** At least 5 days

**Method:** Local Lymph Node Assay in Mice

**Summary:**

1. Based on these findings and on the evaluation system used, Lysol All Purpose Cleaner Trigger Lemon is considered to be a positive contact sensitizer.
2. Classification: Acceptable

**Procedure (Deviations from 870.2600):**

- The laboratory reported that "there were no deviations from the protocol that affected the quality or outcome of the study."
- The guidelines state that, in all instances, the tester must document that appropriate techniques were used to facilitate test substance adherence to the mouse ear for an adequate exposure duration. The laboratory did not document the techniques used to facilitate test substance adherence.
- The guidelines state that female mice should be nulliparous and non-pregnant. The laboratory did not indicate whether the female animals used in the study were nulliparous and non-pregnant.
- The guidelines state that, in addition to an assessment of the magnitude of the ratio estimate, Stimulation Index (SI), statistical analyses which include both an overall assessment of the dose-response relationships and pair-wise comparisons of the SIs of each group should be conducted. The laboratory did not document whether these statistical analyses were performed.
- The body weight mean and associated error term for each group of animals were not provided.
- The group mean dpm/mouse for each treatment group and control group were provided; however, the associated error term was not calculated.

**Procedure:**

Test Substance Preparation and Administration: Healthy mice were released from quarantine prior to testing. Five females were selected for each of three treatment groups (Groups I-III). On Days 1, 2, and 3, each test animal in its group received an open application of 25  $\mu$ L of an appropriate dilution (25% or 50%) of the test substance, or the undiluted test substance, to the dorsum of both ears. The vehicle control group (5 females) was treated in the same way as the test animals, but with vehicle alone (acetone: olive oil) instead of test substance. The positive control group (5 females) was treated with 80% alpha-hexylcinnamaldehyde in acetone: olive oil.

All test and control animals were given a two-day rest period on Days 4 and 5.

Injection of Tritiated Methyl-Thymidine

On Day 6 of the study, all test and control animals were injected in the tail vein with 250  $\mu$ L of 0.01 M phosphate-buffered saline (PBS), pH 7.4, containing 20  $\mu$ Ci of [methyl,  $1^1$ ,  $2^1$ - $^3$ H] Thymidine. Five hours after the injection, the animals were sacrificed, the draining auricular lymph nodes were excised and pairs from each individual animal were processed.

Suspension Preparation and DPM Determination

A single cell suspension was prepared by gentle mechanical disintegration through 200 mesh stainless steel gauze. The cells were washed twice with an excess of PBS and precipitated with 5% trichloroacetic acid (TCA) at 4°C for 18 hours. The pellets were re-suspended in 1 mL of TCA and transferred to 10 mL of scintillation fluid. Incorporation of tritiated thymidine was measured by liquid scintillation counting as disintegrations per minute (DPM) from the paired lymph nodes of each animal, and the mean DPM/animal was calculated for each group.

#### Body Weights and Observations

Individual body weights were recorded on Day 1 prior to dosing and Day 6 prior to injection. All test and control animals were observed daily for clinical signs of toxicity and any signs of excessive irritation at the test site.

#### **Results:**

There was no effect on body weight gain in test group animals during the study. All animals appeared normal for the duration of the study.

The Stimulation Index (SI) or Test/Vehicle Control Ratio derived for each test group based on the group mean DPM are provided below. The test substance produced a SI of  $\geq 3$  in one group of test animals and, therefore, is considered a sensitizer (defined as producing a positive response).

<b>Animal Group</b>	<b>Test Substance Concentration</b>	<b>Average Count per Mouse</b>	<b>Number of Mice in Group</b>	<b>Test/Vehicle Control Ratio</b>
<b>Vehicle Control</b>	NA	608	5	NA
<b>Test Group I</b>	25%	1384	5	2.3
<b>Test Group II</b>	50%	1694	5	2.8
<b>Test Group III</b>	100%	2786	5	4.6
<b>Positive Control</b>	NA	8308	5	13.7*

NA - Not applicable

\* Positive control used to confirm animal sensitization potential and validate procedures.



### Body Weights and DPM Counts

Animal Tail-Tip Color Code	Day of Study		DPM Count
	Day 1 Weights	Day 6 Weights	
Vehicle Control			
Purple	23.8	24.9	719.6
Orange	22.4	22.8	633.8
Blue	23.7	24.1	719.6
Green	22.5	23.1	337.9
Black	21.8	23.0	628.3
Test Group I – 25% conc.			
Purple	24.0	25.0	667.7
Orange	23.1	25.6	1094.7
Blue	20.7	21.7	2364.1
Green	22.5	24.5	1243.9
Black	20.0	20.3	1548.2
Test Group II – 50% conc.			
Purple	23.2	23.7	1456.7
Orange	24.5	24.6	2065.0
Blue	23.6	24.5	2029.8
Green	23.3	24.0	1479.6
Black	20.4	21.5	1437.3
Test Group III – 100% conc.			
Purple	24.2	24.7	1832.4
Orange	23.4	24.3	5308.4
Blue	23.7	24.9	2904.3
Green	22.3	23.4	1647.3
Black	21.8	22.8	2239.8
Positive Control			
Purple	20.0	20.0	6739.5
Orange	23.0	24.1	6961.6
Blue	23.7	23.1	3485.0
Green	23.0	23.4	9719.1
Black	22.1	22.6	14634.7